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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,410	12/14/2001	Peggy J. Farnham	960296.97401	1459

7590

07/20/2006

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,410	Applicant(s) FARNHAM ET AL.	
	Examiner MISOOK YU, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,6,7,9,11-13 and 19 is/are pending in the application.
 4a) Of the above claim(s) 6,7 and 9 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-4 and 19 is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet.</u> |

Continuation of Attachment(s) 6). Other: Sequence alignment (Exhibit A, 3 pages).

DETAILED ACTION

Claims 6, 7 and 9 are withdrawn for reason of record from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 2-4, 6, 7, 9, 11-13, and 19 are pending. Claims 2-4, 11-13, and 19 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This Office action contains new grounds of rejection.

Claim Rejections - 35 USC § 112

Claims 11-13 **are rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11-13 are drawn to a genus of nucleic acid molecules that are hybridized to the coding sequence of SEQ ID NO: 1 or 3 under the recited conditions.

Applicant argues that claim 11 has been amended to limit the oligonucleotide and polynucleotide to those that hybridize to a coding sequence of SEQ ID NO:1 and a coding sequence of SEQ ID NO:3 under much more stringent hybridization conditions. The specific coding sequences of SEQ ID NO:1 (nucleotides 35-859) and SEQ ID NO:3 (nucleotides 1-825) along with the newly recited, much more stringent hybridization conditions put a structural limitation (i.e., nucleotide sequence limitation) on the nucleic acid molecules that can hybridize.

These arguments have been fully considered but found unpersuasive because the instantly claimed partial structure in the form of recited hybridization conditions does not have any functional characteristic associated with. The specification must provide sufficient distinguishing identifying characteristics of the genus other than the partial structures in order to provide an adequate written description. The specification fails to provide functional characteristics, and/or structure/function correlation for the claimed genus. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO: 1 and 3. Therefore, only isolated nucleic acid comprising SEQ ID NO: 1 and 3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

All other rejections not repeated here are withdrawn in view of the amendment.

Claims 11-13 **remain rejected** under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, 3, and nucleic acids encoding SEQ ID NO: 2, and 4, does not reasonably provide enablement for any other nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The scope of enablement rejection is made because the nature of the invention is interpreted as drawn a genus of nucleic acid hybridizing to the coding sequence of SEQ ID NO: 1 or 3.

Applicant argues that claim 11 has been amended to limit the oligonucleotide and polynucleotide to those that hybridize to a coding sequence of SEQ ID NO:1 and a coding sequence of SEQ ID NO:3 under much more stringent hybridization conditions. The specific coding sequences of SEQ ID NO:1 (nucleotides 35-859) and SEQ ID NO:3 (nucleotides 1-825) along with the newly recited, much more stringent hybridization conditions put a structural limitation (i.e., nucleotide sequence limitation) on the nucleic acid molecules that can hybridize.

These arguments have been fully considered but found unpersuasive.

The specification does not teach how to use the nucleic acid molecules that are not overexpressed in liver tumor. The claimed polynucleotide in claims 11-13 as currently construed does not necessarily have to be overexpressed.

The breadth of the claimed invention is broad including many unknown species.

Claim Rejections - 35 USC § 102, Withdrawn

The rejection of claims 11-13 under 35 U.S.C. 102(b) as being anticipated by Wu et al., (April 12, 1996, Biochim Biophys Acta. Vol. 1315, issue no. 3, pages 169-75) is withdrawn in view of the amendment.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 102

Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by US 6639063 B1 filed on July 21 2000, issued Oct 28, 2003.

Claim 11 is drawn to a kit comprising a polynucleotide hybridizing to the coding sequence of SEQ ID NO: 1 or 3.

US 6639063 teaches a polynucleotide that would hybridizes to the coding sequence of SEQ ID NO; 3. Note that attached sequence alignment (total 3 pages, Exhibit A) shows that several sequences disclosed in the patent matches 100% between 74-110 nucleotides. As for control in the claim, the patent at paragraph 460 discloses "The visualization of tissue specific antigen binding at levels above those seen in control tissues to one or more tissue specific antibodies, directed against the polypeptides encoded by EST-related nucleic acids, positional segments of EST-related nucleic acids or fragments of positional segments of EST-related nucleic acids or antibodies against the EST-related polypeptides, fragments of EST-related polypeptides, positional segments of EST-related polypeptides, or fragments of positional segments of EST-related polypeptides, can identify tissues of unknown origin, for example, forensic samples, or differentiated tumor tissue that has metastasized to foreign bodily sites."

Allowable Subject Matter

Claims 2-4 and 19 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642

Exhibit A

Page 1 of 3

RESULT 1

US-09-621-976-11241/c
 ; Sequence 11241, Application US/09621976
 ; Patent No. 6639063
 ; GENERAL INFORMATION:
 ; APPLICANT: Dumas Milne Edwards, J.B.
 ; APPLICANT: Jobert, S.
 ; APPLICANT: Giordano, J.Y.
 ; TITLE OF INVENTION: ESTs and Encoded Human Proteins.
 ; FILE REFERENCE: GENSET.054PR2
 ; CURRENT APPLICATION NUMBER: US/09/621,976
 ; CURRENT FILING DATE: 2000-07-21
 ; NUMBER OF SEQ ID NOS: 19335
 ; SOFTWARE: Patent.pm
 ; SEQ ID NO 11241
 ; LENGTH: 358
 ; TYPE: DNA
 ; ORGANISM: Homo sapiens
 US-09-621-976-11241

Alignment Scores:

Pred. No.:	1.4e-17	Length:	358
Score:	25.00	Matches:	25
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	9.1%	Indels:	0
DB:	3	Gaps:	0

US-10-017-410-2 (1-275) x US-09-621-976-11241 (1-358)

Qy	12	AlaGlySerSerGluValAspTrpCysGluAspAsnTyrThrIleValProAlaIleAla	31
Db	78	GCTGGTAGCTCGGAGGTGGACTGGTGCGAGGACAACACTACACCATCGTGCCTGCTATCGCC	19
Qy	32	GluPheTyrAsnThr	36
Db	18	GAGTTCTACAACACG	4

283

RESULT 1

US-09-621-976-11241/c
 ; Sequence 11241, Application US/09621976
 ; Patent No. 6639063
 ; GENERAL INFORMATION:
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 ; APPLICANT: Jobert, S.
 ; APPLICANT: Giordano, J.Y.
 ; TITLE OF INVENTION: ESTs and Encoded Human Proteins.
 ; FILE REFERENCE: GENSET.054PR2
 ; CURRENT APPLICATION NUMBER: US/09/621,976
 ; CURRENT FILING DATE: 2000-07-21
 ; NUMBER OF SEQ ID NOS: 19335
 ; SOFTWARE: Patent.pm
 ; SEQ ID NO 11241
 ; LENGTH: 358
 ; TYPE: DNA
 ; ORGANISM: Homo sapiens
 US-09-621-976-11241

Query Match 13.1%; Score 108.4; DB 3; Length 358;
 Best Local Similarity 99.1%; Pred. No. 1.3e-22;
 Matches 109; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

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Qy      1 ATGGGCGCCCCGCACTGGTGGGACCAGCTGCAGGCTGGTAGCTCGGAGGTGGACTGGTGC 60
          |||
Db     111 ATGGGCGCCCCGCACTGGTGGGACCAGCTGCAGGCTGGTAGCTCGGAGGTGGACTGGTGC 52

Qy      61 GAGGACAACCTACACCATCGTGCCTGCTATCGCCGAGTTCTACAACACGAT 110
          |||
Db      51 GAGGACAACCTACACCATCGTGCCTGCTATCGCCGAGTTCTACAACACGGT 2

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RESULT 1

US-09-621-976-11241/c
 ; Sequence 11241, Application US/09621976
 ; Patent No. 6639063
 ; GENERAL INFORMATION:
 ; APPLICANT: Dumas Milne Edwards, J.B.
 ; APPLICANT: Jobert, S.
 ; APPLICANT: Giordano, J.Y.
 ; TITLE OF INVENTION: ESTs and Encoded Human Proteins.
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 ; CURRENT FILING DATE: 2000-07-21
 ; NUMBER OF SEQ ID NOS: 19335
 ; SOFTWARE: Patent.pm
 ; SEQ ID NO 11241
 ; LENGTH: 358
 ; TYPE: DNA
 ; ORGANISM: Homo sapiens
 US-09-621-976-11241

3 103

Alignment Scores:

Pred. No.:	2.13e-29	Length:	358
Score:	36.00	Matches:	36
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	13.1%	Indels:	0
DB:	3	Gaps:	0

US-10-017-410-4 (1-275) x US-09-621-976-11241 (1-358)

Qy	1 MetGlyAlaProHisTrpTrpAspGlnLeuGlnAlaGlySerSerGluValAspTrpCys	20
Db	111 ATGGGCGCCCCGCACTGGTGGGACCAGCTGCAGGCTGGTAGCTCGGAGGTGGACTGGTGC	52
Qy	21 GluAspAsnTyrThrIleValProAlaIleAlaGluPheTyrAsnThr	36
Db	51 GAGGACAACCTACACCATCGTGCCTGCTATCGCCGAGTTCTACAACACG	4